

Remarks/Arguments

Applicants have received and carefully reviewed the Office Action of the Examiner mailed September 22, 2008. Currently, claims 1-30 remain pending of which claims 1-8 and 21-30 were previously withdrawn. Claims 9-20 have been rejected. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections – 35 USC § 103

Claims 9 and 13 were rejected under 35 U.S.C. 103(a) as being unpatentable over Shortt (U.S. Patent No. 6,948,223) in view of Morales (U.S. Patent No. 5,920,975). After careful review, Applicant must respectfully traverse this rejection.

“All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP § 2143.03). The Examiner acknowledges that “Shortt fails to disclose crimping the stent onto the balloon as the step of crimping is done prior to the stent being placed over the balloon according to the disclosure of Stiles.” (The Stiles reference is not identified in the rejection and cannot be identified at this time. If the Examiner intends to rely upon Stiles, she is invited to identify the reference in a future non-final Office Communication.) Further, The Examiner acknowledges that “Shortt does not expressly disclose that the diameter of this first portion is greater than or equal to the inner diameter of the second section.” In addition to these acknowledged deficiencies, Shortt requires a heat set step not found in independent claim 9 and teaches a variety of heat set moulds

requiring four mould inside diameter sections in Fig. 2, seven mould inside diameters in Figs 3-4, and at least four mould inside diameters in Figs. 5 and 6.

Morales is said to supply only crimping a stent onto the balloon, presumably prior to introduction into the heated mould method of Shortt, and so does not overcome the multiple deficiencies of Shortt identified above.

In discussing Shortt in view of Morales, the Examiner has consistently characterized the disclosure of Shortt in the most general of terms and has failed to note that the disclosure of Shortt requires a heating step found, for example, in the presence of a hot block in claim 1 of Shortt as well as throughout the disclosure. At col. 2, lines 60-61, the Summary of the Invention, the use of the apparatus of Shortt is described as requiring both pressure and heating. See also col. 3, lines 3-5 where suitable heating means are discussed and the heating means discussion is amplified at col. 4, lines 8-14. The mould (10) of Fig. 6 is characterized as a “heat set mould” at col. 4, line 28. The prior art provided by Shortt discussed at col. 2, lines 37-41 and illustrated in Fig. 2, as cited by the Examiner also requires a heat set step to secure the stent to the balloon. To the extent that Shortt can be said to teach a method for fabricating a balloon catheter stent deployment system, it necessarily appears to require a heat set step not found in claim 9 of the pending application, said heat set step apparently being necessary in that method to prevent elastic recovery of the balloon. Omission of an element with retention of the element's function is an indicia of unobviousness. (MPEP 2144.04, II., B.) Further, although the claims of Shortt only require a mould having two sections, the methods taught and disclosed by Shortt in conjunction with the moulds depicted in Figs. 1-6 appear to require a minimum of four sections of varying diameter, in combination with

heat and pressure, to achieve stent retention features created by the method of pending claim 9 which uses a stepped enclosure having two sections and a process requiring no heating step. Since the method disclosed by Shortt appears to require both providing additional sections and a heat set step, pending claim 9 appears to be unobvious in view of Shortt. Omission of the heat set step required in the method disclosed by Shortt would also appear to impermissibly alter the principle of operation of the method disclosed by Shortt. (MPEP 2143.02, VI.) The apparatus and method of Morales, which appears to supply only crimping a stent onto the balloon, do not appear to overcome the multiple deficiencies of the disclosure of Shortt. For at least these reasons, Applicants respectfully request that the rejection of claim 9 be withdrawn.

Additionally, for similar reasons, as well as others, claims 10-20, which depend from claim 9 and include significant additional limitations, are believed to be patentable over Shortt in view of Morales and Applicant respectfully requests withdrawal of the rejection. If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03)

In considering the Examiner's Response to Arguments, Applicants note that the discussion in question was directed toward the Examiner's incomplete identification of the claim elements said to be present in Shortt. Specifically, in item 5. of the Communication mailed March 26, 2008, the Examiner identified a "distal end of outer shaft (30)"; however a full text search of Shortt for "30" does not find the element in

question and Applicants were unable to find an element bearing a reference number greater than 17 in the Figures. Speculating that the Examiner had misidentified the elements of unnumbered Figure 1, Applicants addressed an apparent failure to provide elements corresponding to the inner and outer shafts. The Examiner no longer refers to element (30) and now appears to rely upon Figure 2 (free of reference numbers) for the inner and outer shafts. In doing so, the Examiner now appears to rely upon a subset of the TFE tubes, 21 and 22, to provide the two diameter stepped enclosure of pending claim 9. In doing so the Examiner attempts to ignore that the method taught by the prior art disclosure of Shortt appears to require an enclosure having four, or more, inside diameters to achieve the result obtained by the method of claim 9 with only two sections and without the heating step referred to at page 14 of the Response of March 26, 2008 and required by each of the methods disclosed by Shortt.

In responding to Applicant's analysis of the correspondence proposed by the Examiner between the first section (41) and second section (42) of the enclosure of claim 9 and the various elements of Figure 2 of Shortt, the Applicants noted that the proposed method would require that the balloon expand to contact "2nd TFE" identified by reference numeral 21 in the text at column 2, lines 20-21 which describes Figure 1 where "2nd PROX TFE" is identified. As clearly may be seen in Fig. 2, the balloon does not contact "2nd TFE", but rather only contacts "3rd CENTER TFE" which appears to correspond to the element identified by the Examiner by reference numeral (22) which was said to be equivalent to the second section of the enclosure. Applicants correctly noted that the "pillow gap" formed by heat setting the balloon against the "3rd CENTER TFE" appears to prevent the balloon from expanding sufficiently to contact the "2nd

PROX TFE” as would be required to provide the necessary step of the method of claim 9. The Examiner further argues that Figure 7a of Shortt demonstrates that inflation of the balloon causes it to engage the first section of the enclosure (“2nd TFE”). Figure 7a shows no such contact and had such contact occurred, one would expect to find a heat set flat in the PROXIMAL PILLOW of that figure. Instead, one only finds an unrestricted curve.

The Examiner refers to paragraph 6 of the Office Action mailed March 26, 2008 which attempted to assert that the existence of some portion of the distal section of the balloons of Shortt which has a maximum outer diameter no greater than the initial outer diameter of the stent is sufficient to provide a distal section which has a maximum outer diameter no greater than the initial outer diameter of the stent. Within claim 9, the distal section of the balloon is described as that portion “uncovered by the stent”. Clearly, in each of the Figs. 2, 7a, 7b, and 7c in which the diameter of the balloon distal of the stent may be determined, that diameter is larger than the outer diameter of the stent. Further, the Examiner’s reliance upon the presence of the “4th TFE” in Figure 2 of Shortt requires a method employing an enclosure having at least three inside diameters. In this regard, the Examiner argues that the “4th TFE” in Figure 2 may be considered part of the second section of the stepped enclosure “since it is not required that the second section has a continuous inner diameter.” The current claim language, “a second section having a second inner diameter” and “the second inner diameter being greater than the initial outer diameter of the stent” would appear to be sufficiently clear that the diameter is single valued, particularly in the context of describing an enclosure having two inner diameters which are differentiated by the claim rather than simply providing an enclosure.

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Date:

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